

EXHIBIT 28



Cephalon, Inc
41 Moores Road
Frazer, PA 19355
tel 610 344 0200
fax 610 344 0065
www.cephalon.com

Memo

To: Legal Department - Archives
From: Kimber Titus x86766
Date: December 15, 2006
Re: Fully-Executed Agreement(s) for Archiving in Central Files

I have attached hereto a fully executed agreement for archiving in Central Files.

I have completed the checklist below in preparation for archiving in Central Files:

- ☒ An authorized Cephalon officer has signed the agreement(s) (at the level of Vice President or above. If this is a CDA, a Director or Senior Director may be authorized to sign if a valid Delegation of Authority to sign CDAs is on file in the Legal Department).
- ☒ The agreement(s) is fully executed by both parties and both original signatures are attached.
- ☒ The signature page contains the Legal Department approval stamp, which signifies that the agreement(s) was routed to Legal for review and approval prior to signature.

Thank you!



INDEPENDENT EDUCATIONAL PROGRAM ("IEP") GRANT AGREEMENT

This Agreement is entered into as of this 28th day of November, 2006 by and between Cephalon ("Cephalon"), located at 41 Moores Road, Post Office Box 4011, Frazer, PA 19355, and Boston University School of Medicine ("IEP Provider") located at 715 Albany Street, A305, Boston, MA 02118, American Academy of Pain Medicine ("Sponsor of the 23rd Annual Meeting") located at 4700 W. Lake Avenue, Glenview, IL 60025 and Fusion Medical Education LLC ("Educational Partner") located at 301 Edgewater Place, Suite 300, Wakefield, MA 01880.

WHEREAS, Cephalon has reviewed IEP Provider's grant request to support a medical education program ("Program"); and

WHEREAS, Cephalon has determined that the Program has the potential to significantly further medical knowledge and improve patient care; and

WHEREAS, it is the intent of the parties to ensure that the Program will be independent, objective, balanced and scientifically rigorous, so that it will not be viewed by the United States Food and Drug Administration ("FDA") as promotional and that Cephalon will not be viewed as responsible for its content; and

WHEREAS, Cephalon agrees to provide funding for the Program under the conditions set forth below

NOW THEREFORE, IEP Provider and Cephalon agree to the following terms under this Agreement:

1. Title of Program. The IEP is entitled, "Chronic Pain Management with Opioids: Strategies to Improve Communication Between Caregivers and Patients" to be presented at the 2007 AAPM Annual Meeting and a copy of the grant request for the Program is attached hereto as Exhibit A.
2. Type of Program. The Program is:
☒ accredited (e.g., continuing medical education or "CME"); or
☐ an independent program where CE credits will not be offered.
3. IEP Provider. The IEP Provider is the following type of entity:
☐ Accredited continuing medical education provider
☒ University/Hospital
☐ Professional Organization
☐ Medical Education Company



4. Educational Partner. The IEP Provider X shall ____ shall not use a third party that will provide assistance in support of the Program ("Educational Partner"). The name of the Educational Partner is Fusion Medical Education LLC.
5. Educational Components. The expected components of the Program (e.g., number of live meetings, CD ROM, web-based, etc.) are as follows:
 - (a) 2007 AAPM Annual Meeting;
6. Program Purpose. The Program is for scientific and educational purposes only and is not intended to promote a Cephalon product directly or indirectly. The Program is not a repeat performance of a prior program.
7. Grant Amount Funding Arrangements.
 - (a) Cephalon will provide support for the Program by means of an educational grant in the total amount of \$263,975. If the Program is canceled or terminated prior to completion, IEP Provider shall return the grant, or any unused portion thereof, to Cephalon within thirty (30) days of such termination or cancellation. IEP Provider shall have full responsibility for all funding arrangements of the Program, including any funding to be provided to IEP Provider's Educational Partner. Payment of the grant shall be made in accordance with a schedule agreed to by the parties. All payments due hereunder shall be made by Cephalon within forty-five (45) days of its receipt of an invoice for same, provided IEP Provider is in compliance with the terms of this Agreement. IEP Provider hereby directs Cephalon to pay the full grant amount of the grant to its Educational Partner at the following address: 800 Township Line Road, Suite 250, Yardley, PA 19067.
 - (b) Within thirty (30) days of completion of the Program, IEP Provider shall provide Cephalon with a detailed reconciliation of actual out-of-pocket expenses incurred, and to the extent Cephalon has overpaid IEP Provider for same, IEP Provider shall provide a refund to Cephalon within thirty (30) days thereafter. Such detailed reconciliation shall be forwarded to Cephalon at the address above to the attention of Rod J Hughes, Ph.D., Vice President, Scientific Communications.
 - (c) IEP Provider may not use funds provided by Cephalon to pay travel, lodging, honoraria or personal expenses for non-faculty attendees. Grant funds may be used to reduce the overall registration fees for attendees. Grant funds may not be used to purchase capital equipment or to provide general operational support for an institution. Funds for hospitality shall not be provided except that funds may be used for modest meals or receptions that are held as part of the Program, but such events shall not compete with nor take precedence over educational events. The appropriateness of any reception shall be at the sole discretion of the IEP



Provider, and IEP Provider shall have final decision making authority in connection with any such activities.

(d) Funds may be used by the IEP Provider to permit medical students, residents, fellows or other health care professionals in training to travel to and attend the Program; provided, however, that the selection of such students, residents or fellows who receive funds is made by either the academic or training institution or, if by the IEP Provider, such selection shall be made with the full concurrence of the academic or training institution

(e) In accordance with the Accreditation Council for Continuing Medical Education ("ACCME") Standards and to assist Cephalon in complying with its internal auditing procedures, IEP Provider agrees to verify the manner in which the grant is used. Accordingly, within thirty (30) days following a request from Cephalon, IEP Provider shall provide to Cephalon.

- i. A written statement verifying that the Program occurred, and
- ii. An itemized list of expenditures supported by the grant.

8 Objectivity and Balance. IEP Provider shall retain full responsibility for control of the content of the Program and shall ensure that the following requirements are met:

(a) The Program material/information will be objective, balanced and free from commercial bias. All topics shall be treated in an impartial, unbiased manner. All discussions shall include a range of views about each class of drug and disease treatment options. Information shall not unfairly represent a spectrum of views favoring a product or class of products marketed by Cephalon or any other company. The title of the Program will fairly and accurately represent the scope of the presentation.

(b) IEP Provider agrees that neither Cephalon nor its agents shall control the content of the Program. IEP Provider agrees that there will be no scripting, targeting of points for emphasis, or other activities by Cephalon or its agents that are designed to influence the content of the Program. If requested in writing by the IEP Provider, medical/scientific representatives from Cephalon may attend content development meetings or other planning meetings, for the purpose of addressing any scientific inaccuracies they observe. Personnel from Cephalon must not discuss or in any way attempt to control (either during the meeting or at breaks or meals), the content of the program. An appropriate medical/scientific representative from Cephalon may provide a presentation at a content development meeting at the request of the provider, or may respond to specific questions at such meeting regarding the results of a Cephalon-sponsored research study, provided the information presented conforms to the generally accepted standards of experimental design, data collection and analysis, and provided any



presentation is accompanied by a detailed outline of the presentation, which can be used by the IEP Provider/Educational Partner to confirm the scientific objectivity of the presentation.

- (c) If the IEP Provider, in its sole discretion, requests a Cephalon medical representative to review the Program for medical accuracy and completeness, Cephalon will comply with such request. The parties acknowledge there is no obligation or any condition requiring IEP Provider to make such a request. Any such request must be made after the Program materials are fully developed and such request must be made by the IEP Provider only to a Cephalon medical representative that has responsibility for the therapeutic area that will be covered by the Program. IEP Provider will not ask any marketing or sales representatives at Cephalon to comment on the material. All final decisions regarding whether to modify the material based on any comments provided by the Cephalon medical representative shall be in the sole discretion of IEP Provider.
 - (d) If a product marketed by Cephalon is the subject of discussion, the data will be objectively selected and presented, with an accurate reflection of favorable and unfavorable information about the product and shall also include a balanced discussion of prevailing information on alternative products and /or therapies.
 - (e) Any suggestions of superiority of one product or treatment over another will be supported by the body of available data, and will not result from selective presentation or emphasis on data favorable to particular treatment
 - (f) IEP Provider represents that neither it nor the Educational Partner (if any) has either an open complaint or decision from the ACCME or the Food and Drug Administration that a program provided by the IEP Provider or the Educational Partner failed to meet standards of independence, balance, objectivity, or scientific rigor.
9. Risk Minimization Action Plan. Cephalon provides the following Risk Minimization Action Plan ("RiskMAP") information to all IEP Providers. Neither Cephalon nor its agents shall influence or control whether a product marketed by Cephalon is the subject of discussion. A RiskMAP is a strategic safety program designed to meet specific goals and objectives in minimizing known risks of a product while preserving its benefits. Any product marketed by Cephalon that is approved with a RiskMAP, and the key safety-related health outcomes outlined in that RiskMAP, are listed in Exhibit B. IEP Provider agrees that it is aware of the RiskMAP(s) and the key safety messages.
- 10 Faculty Selection. IEP Provider shall retain full responsibility for the selection of the presenters, authors, moderators, and/or other faculty (hereinafter referred to collectively as "Faculty"). Cephalon, through its Scientific Communications Department, may respond only to IEP Provider-initiated, written requests (or



requests from the Educational Partner) for suggestions of Faculty or sources of possible Faculty. In response to such requests at least three (3) names will be suggested (if possible) for each open position and this information will be provided in writing. IEP Provider will record the role of Cephalon in suggesting Faculty; will seek suggestions from other sources; and will make its selection of Faculty based on objective criteria. IEP Provider shall not be obligated to request or accept such assistance from Cephalon or its agents as a condition of receiving the educational grant hereunder.

- 11 Disclosures. IEP Provider will ensure meaningful disclosure of limitations of data (e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion). IEP Provider will require that Faculty disclose when a product is not approved in the United States for the use under discussion.
- 12 Question and Answer Session. To the extent the Program is a presentation, IEP Provider will ensure meaningful opportunities for questioning by the audience.
13. Financial Relationships. IEP Provider will ensure meaningful disclosure to the audience of Cephalon funding and any significant relationship between individual Faculty and Cephalon. All meaningful disclosure(s) shall also be made in any written materials, including but not limited to announcements, brochures, syllabi and enduring material. Disclosures shall not mention product trade names.
- 14 Metrics/Copies of Program Material.
 - (a) IEP Provider and/or Educational Partner shall provide certain outcome measurements and metrics to Cephalon as requested by the Scientific Communications Department. Such metrics shall be provided either after the conclusion of a single live event or monthly for a year-long accredited program and may at Cephalon's request include the number of program participants, number of certifications, assessment of the program and faculty, and demonstration of learning by program participants.
 - (b) After the Program has occurred, IEP Provider shall provide Cephalon with 5 copies of all Program materials in CD ROM or electronic format and 20 copies in print format.
15. Representations and Warranties. IEP Provider represents that:
 - (a) Neither it nor the Educational Partner, if any, provides marketing, advertising, public relations, market research, medical education services or other consulting services (e.g., support for advisory boards) to any other department within Cephalon ("Marketing Activities");
 - (b) If IEP Provider or the Educational Partner has an affiliated company that provides Marketing Activities to Cephalon, IEP Provider has instituted appropriate controls and safeguards to ensure the Program (i) remains independent, objective, balanced and scientifically rigorous, (ii) is not intended to promote a Cephalon product directly or indirectly, and (iii) is



not in any way biased due to the affiliated company's relationship with Cephalon;

- (c) IEP has determined that it is appropriate to use the Educational Partner in light of the requirements under this Agreement; and
- (d) If IEP Provider or its Educational Partner employs a former Cephalon employee who worked at Cephalon anytime during the most recent year and who had marketing responsibility in the therapeutic area that will be covered by the Program, then that former employee will not have any role in the planning, development or delivery of the Program.

16. Invitations/Enduring Materials. The Program audience will be selected by the IEP Provider. The IEP Provider shall be responsible for distributing materials about the Program, including invitations, reminder notices, and business reply cards that can be used by third parties to obtain any enduring Program material from the IEP Provider.

17. Ancillary Promotional Activities. To the extent the Program is a live presentation, no promotional activities or product advertisements will be permitted in the same room as or in an oblique path to the Program. If the Program is a teleconference or webcast, no product advertisements or promotional activities will be permitted immediately prior to, during, or immediately after the delivery of the Program. If the Program is in print format, no product advertisements or promotional materials will be interleaved within the pages of the Program. If the Program is made available electronically, no product advertisements or promotional materials will appear within the Program material or interleaved between computer windows or screens of the Program

18. Compliance with Guidelines. IEP Provider represents that the Program, including development of the Program and Program materials, shall conform to the American Medical Association ("AMA") Guidelines on Gifts to Physicians, the AMA Ethical Opinion on Continuing Medical Education, the ACCME Standards for Commercial Support, the FDA December 3, 1997 Final Guidance for Industry-Supported Scientific and Educational Activities, and the Pharmaceutical Research and Manufacturers Association ("PhRMA") Code on Interactions with Healthcare Professionals.

19. Logistical Status Reports. IEP Provider and/or Educational Partner shall provide periodic reports to Cephalon regarding the management and logistics of program components.

20. Miscellaneous.

- (a) No party shall use the other party's or its affiliates' name or trademarks for publicity or advertising purposes, except with the prior written consent of the other party.



- (b) IEP Provider agrees to obtain all consents, authorizations, approvals and releases that may be necessary for the production of the Program and of any written materials prepared in connection therewith. IEP Provider agrees to indemnify Cephalon with respect to any claims, actions or demands, including reasonable attorneys' fees that may arise in any manner out of IEP Provider's failure to secure such consents, authorizations, approvals or releases.
- (c) No term, condition or other provision of any attachment or addendum to this Agreement shall supersede any term, condition or other provision of this Agreement and with respect to any inconsistency or ambiguity, the Agreement shall control.

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IN WITNESS WHEREOF, the parties, by their duly authorized representatives,
agree to comply with all the terms and conditions of this Agreement.

**BOSTON UNIVERSITY SCHOOL OF
MEDICINE**

By: *Julie Mote*

Name:

Title:

The above signatory is a duly authorized
corporate officer of the IEP Provider.

Date:

Tax ID #

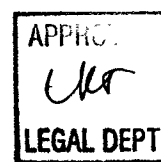
CEPHALON, INC.

By: *Rod J Hughes*

Name: Rod J Hughes, Ph.D.

Title: Vice President, Scientific Communications

Date:



ROVED

S

DATE:

FUSION MEDICAL EDUCATION LLC

By: *Tracy Lasquade*

Name: *Tracy Lasquade*

Title: *Client Service Manager*

The above signatory is a duly authorized
corporate officer of the Educational Partner.

Date: *12/7/06*

Tax ID #: *38 3670784*

AMERICAN ACADEMY OF PAIN MEDICINE

By: *Kathryn Chocey*

Name: *Kathryn Chocey*

Title: *Dir of 1st Rel*

The above signatory is a duly authorized
corporate officer of the Sponsor of the 23rd Annual
Meeting

Date: *12-13-06*

Tax ID #: *36-3874208*

Where Medical Minds Meet



FUSION

301 Edgewater Place ■ Suite 300 ■ Wakefield, MA 01880
Tel 781 246 6646 ■ Fax 781 246 2822
www.fusionmedical.com

A Request for an Unrestricted Educational Grant:

American Academy of Pain Medicine (AAPM)

2007 CME Symposium

*Chronic Pain Management With Opioids:
Strategies to Improve Communication Between Caregivers and Patients*

Chaired by Scott Fishman, MD

Requested 11/1/06 by:

Fusion Medical Education LLC and

Boston University School of Medicine



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Program Overview

Fusion Medical Education LLC (Fusion), in collaboration with Boston University School of Medicine, requests that Cephalon provide an unrestricted educational grant to support the development of a satellite symposium entitled *Chronic Pain Management With Opioids: Strategies to Improve Communication Between Caregivers and Patients*. The symposium will be held in conjunction with the next annual meeting of the American Academy of Pain Medicine (AAPM), February 7-10, 2007, in New Orleans, Louisiana. This grant proposal contains a needs assessment justifying the program, learning objectives, program synopsis, agenda topics, and faculty

Topic Rationale and Needs Assessment

Opioids are powerful medications that are available in a variety of formulations to treat acute pain, chronic pain, and breakthrough pain in clinical practice. However, because opioids are also controlled substances, they must be used with caution and great care. Consistent and proactive communication between patients and their caregivers can raise awareness and overcome problems that may arise with opioid use.

Individualized treatment plans and treatment efficacy

Persistent, chronic pain is a widespread problem that, according to a 1998 survey, is a presenting complaint in 22% of primary care patients (Gureje et al, 1998). In a subsequent study undertaken by the American Pain Society, 9% of Americans reported moderate to severe nonmalignant pain (American Pain Society, 2006). And among 228 patients treated at 9 pain clinics in 2004 for nonmalignant pain, 74% complained of episodes of severe or excruciating breakthrough pain (BTP) despite relatively good control of persistent baseline pain (Portenoy et al, 2006). In that series, the single most common type of pain was back pain; however the range of pain types are diverse, and therefore, pain treatment plans must be individualized to the patient. Breakthrough pain also is a common problem for patients with cancer. In one study of 164 cancer patients with controlled chronic pain, 51.2% had experienced at least one breakthrough pain episode during the previous day (Portenoy et al, 1999). The median number of episodes was 6, and the median interval from onset to peak pain was 3 minutes.

Although nonpharmacologic treatment strategies and nonopioid medical therapies are the first therapeutic considerations for most pain patients, patients with moderate to severe persistent pain, particularly those with breakthrough pain, will usually require opioid treatment if they are to realize significant improvement in their functional abilities (Devulder et al, 2005). However, there are significant impediments to the use of opioid pain medications that limit their use in patients who would greatly benefit. Indeed, the undertreatment of pain has formally been recognized as a significant contemporary healthcare problem by several government agencies, including the Agency for Health Care Policy and Research and the Joint Commission on Accreditation of Healthcare Organizations (Sinatra, 2006). Some argue that cost, especially of some of the newer opioid formulations, is one of the most important barriers to effective pain management. But recent studies suggest that the failure to effectively manage pain, with opioid pain medications when necessary, actually increases the overall healthcare costs incurred by the patient (Chandler & Payne, 1998). This in large part is due to the frequent emergency department visits of patients with poorly controlled pain.

Differentiating Chronic, Acute, and Breakthrough Pain

The true prevalence of persistent pain or BTP is not entirely clear because there is no general agreement, even among pain specialists, regarding the definition of the various types of pain. The definition of breakthrough pain is crucial, as the selected definition has an important impact on the population of interest, prevalence of BTP, treatment recommendations, and research strategies. Until widely recognized and accepted definitions of BTP, acute pain, or persistent pain are constructed, it will remain important that clinicians have the prevailing distinctions between the various types of pain clearly described in order that they may best communicate their rationale for treatment methods to their patients.

Opioid Side Effects

Side effects of opioid use are another common concern among both healthcare providers and patients. In her book on pain management, Janet Abrahm listed misconceptions about healthcare providers' ability to prevent side effects as 1 of the 4 most important patient fears about opioids (Abrahm, 2005). For example, patients may recall a negative prior experience when taking a mild opioid, such as severe nausea or constipation with codeine given for back pain. But side effects such as nausea are usually related to a specific opioid formulation and may not occur with use of a different formulation. Constipation is effectively treated with the use of a laxative, titrating the intermediate or long-acting opioid to the lowest effective dose, and in some cases using very short acting opioid compounds if BTP is the primary problem. But despite the fact that these are some of the most well-known side effects of opioids, physicians often neglect to address them (Abrahm, 2005).

Communication

Because opioids have the potential for both patient benefit and abuse, there are special considerations for using them in patients with chronic pain that should be anticipated and managed by physicians. Patient responses to opioids can vary, in part because genetic factors likely influence pain perception and the effect of analgesia (Mogil, 1999). Tolerance to opioids can arise as a result of pharmacokinetic adaptations, such as increased drug clearance, or pharmacodynamic adaptations, such as reduced responsiveness of opioid receptors to the opioid (Dews & Mekhail, 2004). In addition, in at least some patients, high doses of opioids can produce hyperalgesic effects (Cherny et al, 2001). Because of the many factors that can affect an individual's response to pain medications, clear and open lines of communication between caregivers and patients are absolutely necessary to provide optimal treatment, furthermore, communication is absolutely essential to address the potential for abuse and dependence (Coombs et al, 1996).

At a symposium presented as part of the American Pain Society Annual Meeting in May 2006, clinician-attendees noted that sections on patient-teaching strategies and patient education were some of the most valuable parts of the symposium. When asked about barriers to incorporating what they learned about opioid pain management into their clinical practice, they noted that communication with patients and colleagues was "a definite barrier." Stated another way, they lamented the lack of an adequate patient education program in their hospital and the low awareness of pain management on the part of their colleagues. Others raised concerns about physician "opioid phobia" and the persistent fear of addiction.

Patients with chronic pain, regardless of clinical management methods, may also experience symptoms or illnesses that can worsen the course of their disease. These might include depression, pain-related fatigue and anxiety, and social withdrawal (De et al, 2006; Taylor et al, 2005). Open communication and discussion can identify these clinical problems and other health issues, awareness of which may assist physicians to develop the most effective treatment plans and minimize their patients' disability (Olsen & Daumit, 2004). Patients with chronic pain should understand that opioids can reduce pain and help increase functioning (Passik & Weinreb, 2000). However, management of patient expectations is required; opioids should not be used with the goal of reducing all psychologic complaints (Marcus, 2000).

Management Tools and Techniques

Many tools and techniques are available to help the clinician use opioids correctly. Assessment tools, opioid agreements, and pain diaries can be leveraged to facilitate communication and also help identify potential misuse/abuse issues. Addiction, misuse, abuse, and diversion are major concerns. Indeed, physician concern about opioid misuse has been described as the most significant barrier to the optimal use of opioids in patients with chronic, noncancer pain (Sinatra, 2006). The risk of addiction appears to be very low when opioid therapy is medically indicated. In one study involving over 100 patients with chronic noncancer pain treated with opioids for a mean of 14 months, the rate of addiction was 2.8% (Cowan et al, 2003). Another study of 150 patients with back pain treated with opioids documented a 2% risk of addiction (Mahowald et al, 2005). Although these rates are low, they are significant enough to prevent some physicians from prescribing opioid therapy. Hence, better education identifying ways to manage these issues would likely improve appropriate treatment.

There are at least 25 different screening tools that have been proposed for use in identifying those patients most at risk for opioid diversion or abuse, but none has been universally accepted (Passik and Kirsh, manuscript in preparation). The CAGE (Beresford et al, 1990) and the Screener and Opioid Assessment for

Patients with Pain (SOAPP) (Akbik et al, 2006), particularly the 14-item version, have been shown to be as reliable and valid as most of the other studies in identifying those at risk. Ultimately, however, the identification of patients who are abusing opioid medications relies on open lines of communication between the patient and physician.

Previous clinical studies indicate several important issues related to persistent baseline and breakthrough pain. First, primary care physicians provide the majority of care to patients with most pain syndromes, including nonmalignant pain, such as back pain, and cancer-related pain. Thus, these physicians need practical clinical information regarding the proper diagnosis and optimal management of pain patients. Second, many clinicians lack critical communication skills or tactics necessary for eliciting critical information about pain symptoms and associated behaviors from their patients. They may even choose to incorporate into their practice one of the various pain assessment scales available for quantifying the severity of pain or the various multidimensional tools, such as the Brief Pain Inventory or pain diary, which can be used to better qualify the pain and its potential causes.

Thus, physicians have important educational needs in differentiating various types of pain, improving communication, managing opioid side effects, and optimizing management. Consequently, Fusion Medical Education proposes a symposium at the American Academy of Pain Medicine (AAPM). This program is aimed at clinicians who primarily manage pain patients and includes practical clinical strategies for communicating with patients and eliciting critical details regarding the nature and possible causes of their pain, associated psychological issues such as depression or fatigue, and potential for drug diversion or abuse. Because the science and technology of pain medicine is expanding at such a rapid rate, even pain specialists have a hard time keeping up with the new concepts about pain transmission, medications, procedures, devices, and therapies (Fishman, 2006). Through a series of succinct and well-coordinated presentations on these topics by nationally recognized pain experts, attendees at the symposium may alter their treatment of patients with persistent and breakthrough components of chronic pain because of an improved understanding of the indications, adverse events, and the addiction and abuse potential of the medications.

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Target Audiences

This symposium is intended for pain specialists and other healthcare providers with a clinical interest in the treatment of persistent baseline and breakthrough pain.

Educational Objectives

At the conclusion of the symposium, participants will be able to

1. Differentiate persistent pain from breakthrough pain, and define both as components of chronic pain
2. Identify side effects of opioid therapy and understand how to manage them
3. Utilize management techniques for fostering responsible opioid use
4. Identify clinical techniques that facilitate communication between patients and healthcare providers regarding the nature and causes of pain, and opioid use
5. Tailor/create individualized treatment plans based on the patient's pain
6. Understand the need for continuous dialogue and treatment efficacy assessment

Program Synopsis

The AAPM CME program *Chronic Pain Management With Opioids: Strategies to Improve Communication Between Caregivers and Patients* has been designed to provide the most practical information to participants for effective communication with patients. The program will provide strategies for patient/physician communication regarding these issues: (1) making pain assessments; (2) clinical management requirements for using opioids to treat chronic pain, and (3) opioid risk management in patients. The program will emphasize methods for communicating with patients about these topics, as well as the importance of listening to patients for clues to optimal pain management

Faculty

(Program chair)
Scott M. Fishman, MD
Chief, Division of Pain Medicine
Professor of Anesthesiology
Department of Anesthesiology and Pain Medicine
University of California, Davis
Sacramento, California

Steven D. Passik, PhD
Associate Attending Psychologist
Memorial Sloan-Kettering Cancer Center
New York, New York

Perry G. Fine, MD
Professor of Anesthesiology
School of Medicine Pain Research Center
University of Utah
Salt Lake City, UT
and
VP, Medical Affairs National Hospice and Palliative
Care Organization
Alexandria, Virginia

Program Agenda

Scott Fishman, MD, chief of the Division of Pain Medicine and associate professor of Anesthesiology at the University of California, Davis, will act as chairperson for this CME program. He is the author of many peer-reviewed publications regarding pain, as well as the book *Listening to Pain: Improving Pain Management Through Communication*, which will be published in the fall of 2006. The following is the program agenda

- 1 Meeting introductions and educational objectives by *Scott Fishman, MD, Chair*
2. Critical communication topics for patients with chronic pain by *Perry Fine, MD*
 - a Assessments pain characterizations
 - i Carefully choosing language to describe pain
 - ii Differentiating chronic pain from episodes of breakthrough pain
 - iii Pain location, duration, radiation, and character: clues for pain management
 - b Using pain management tools to facilitate communication
 - i Pain assessment scales to describe and quantitate pain including numeric rating scales, verbal rating scales, visual analog scales, and picture scales
 - ii Pain diaries to record/describe pain episodes
 - c Special issues in patients with chronic pain
 - i Depression
 - ii Support system
 - iii Fatigue
- 3 Communicating with patients about pharmacovigilance by *Steve Passik, PhD*
 - a Risk management programs for opioids for chronic pain
 - b Opioid agreements and opioid abuse risk assessments
 - i Prescription monitoring (pharmacy profiles)
 - ii Urine screening
 - c Communicating with patients about screening
 - d Listening for clues to aberrant behaviors
 - e What to say (and do) when monitoring identifies drug abuse
- 4 Physician responsibilities opioids for chronic pain by *Scott Fishman, MD*
 - a Physician requirements for prescribing opioids. tailoring treatment for each individual's pain
 - i Tools to manage and document patient outcomes
 - b Expert guidelines for the use of opioids to treat chronic pain
 - i Dosing
 - 1 Opioids commonly prescribed
 - 2 Matching opioid formulations to patients in the outpatient setting (oral intravenous, transmucosal, rectal)
 - 3 Titration
 - 4 Managing the side effects of opioids
 - c Periodic review of opioid treatment efficacy
- 5 Question and answer session

Boston University School of Medicine (CME Accreditor)

Course director James Otis MD, associate professor of neurology, Boston University School of Medicine, Boston, MA

Activity Registration

Preregistration will be available via fax-back form to Fusion Medical Education. It will also be available on the registration Web site

Program Evaluations

The program proposed herein will integrate the use of personal response devices by symposium participants to gauge the educational needs met by the program. Surveys will be administered before and after the symposium to fully evaluate the effectiveness of the program to meet educational objectives and to assess topics for future continuing medical education initiatives.

In addition to our in-depth survey, which asks participants for ideas for future programs, whether the objectives for this program were met, whether or not any commercial bias was perceived, and for individual speaker evaluations, participants are also asked to list 3 changes that they intend to make as a result of the activity. In 1 to 3 months of the CME activity, the participants are contacted via fax or e-mail and are asked if they have fully implemented, partially implemented, or were unable to implement the changes they intended to make.

Fusion's Role

Medical Direction and Slide Support

- Recruit and brief the faculty by phone and written correspondence.
- Maintain a dossier of presenters, including their curriculum vitae.
- Schedule and host faculty conference calls.
- Develop slide template and share with presenters to ensure consistency.
- Create agenda title slides for the meeting.
- Assist faculty with any needs they might have in preparing their presentations
- Copyedit and proofread all faculty presentations prior to meeting
- Host on-site slide review session prior to the symposium.
- Coordinate use of the Audience Response System.

Audience Generation and Meeting Materials

- Create program invitation to mail to congress attendees prior to program date.
- Produce invitation material to reach on-site attendees (in registration bags).
- Develop and produce the following on-site meeting materials:
 - Program title and faculty presentation slide template
 - Program syllabus workbooks for attendees (including agenda, faculty profiles, presentation abstracts, and selected slides from each presentation)
 - Program signage
- Manage creative and production services and distribution of materials, and oversee their shipment to the symposium
- Arrange program advertisement for the symposium (journal TBD)

Creative Design

- Develop creative design for correspondence, materials, signage, slide templates, etc
- Produce and print program books, name badges, tent cards, and signage.

Logistics Management

- Negotiate all contracts for hotel and vendors.
- Manage attendee registration
- Manage faculty travel and logistics.
- Handle faculty honoraria.
- Arrange for meeting room and AV management.
- Distribute program booklets.
- Coordinate logistics with AAPM staff.
- Provide financial management of the educational grant
- Provide a meeting planner on-site to manage all logistics.
- Follow up on faculty-directed requests from the meeting.

- Reconcile all project-related costs according to the terms of the educational grant

CME Accreditation: Boston University School of Medicine

Fusion is the educational partner of Boston University School of Medicine (BUSM). BUSM's role and responsibilities include

- Overseeing development of the CME/CE Program
- Ensuring that the program meets ACCME accreditation criteria
- Approving all audience-generating activities and materials
- Producing and distributing CME/CE certificates in a timely manner to participants

Standards for Commercial Support

Fusion Medical Education, in conjunction with ACCME-accredited providers of CME, follows ACCME standards for commercial support (http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf)

In brief, these standards require that a "CME provider must ensure that the following decisions were made free of the control of a commercial interest. The ACCME defines a 'commercial interest' as any proprietary entity producing health care goods or services, with the exemption of non-profit or government organizations and non health care related companies

- 1 Identification of CME needs;
- 2 Determination of educational objectives,
- 3 Selection and presentation of content;
- 4 Selection of all persons and organizations that will be in a position to control the content,
- 5 Selection of educational methods; and
- 6 Evaluation of the activity "

Fusion Fee**Medical Direction and Slide Support**

Faculty recruitment, correspondence, patient testimonials, and dossier management							\$15,500
Slide development, copyediting, and proofreading							\$26,700
On-site slide review							\$5,000

Audience Generation and Meeting Materials

Audience generation and on-site promotion							\$3,500
Materials development and management							\$12,500

Creative Design

Creative and template design							\$4,500
Materials design and layout							\$8,500

Logistics Management

Hotel and vendor vetting and contracting							\$4,500
Registration management, on-site logistics, and vendor management							\$14,500
Financial management and budget oversight							\$4,500

Fusion Fee Total: **\$99,700**

Third-Party Costs

AAPM symposium fee **\$50,000**

Faculty Honoraria

Chair	1	chair	@	\$3,000	each		\$3,000
Faculty	2	faculty	@	\$2,000	each		\$4,000
							\$7,000

Travel & Expenses

Faculty (including CME course director)

Air travel	4	faculty	@	\$1,000	each		\$4,000
Ground transportation	4	faculty	@	\$250	each		\$1,000
Expenses	4	faculty	@	\$150	each		\$600

Fusion

Air travel	4	staff	@	\$900	each		\$3,600
Expenses	4	staff	@	\$150	each		\$600
							\$9,800

Hotel

Faculty rooms (including CME course director)	4	faculty	@	\$275	x	2	nights	\$2,200
Fusion rooms	4	staff	@	\$275	x	2	nights	\$2,200
								\$4,400

Food & Beverage

Slide review	10	people	@	\$25	each		\$250
Symposium (lunch)	350	attendees	@	\$45	each		\$15,750
							\$16,000

Audio/visual (AAPM vendor)

Includes slide review, symposium, and technician travel/hotel **\$15,000**

Premeeting Audience Generation & Program Materials

Invitations (mailed, door drops, signage pockets)	3,500	pieces	@	\$0.75	each		\$2,625
Postage for recruitment mailing	2,000	pieces	@	\$0.60	each		\$1,200
Symposium program books	400	books	@	\$40	each		\$16,000
AAPM door drop fee							\$3,000
Signage, badges, tent cards							\$1,500
<i>Pain Medicine</i> journal advertisement in Jan/Feb issue							\$2,250
Registration Web site							\$1,000
Congress program advertisement fee							\$2,000
							\$29,575

CME Accreditation

Accreditation & certificate fee							\$16,000
CME course director	1	faculty	@	\$2,500	each		\$2,500
							\$18,500

Miscellaneous

Audience response system							\$8,500
Reference acquisition & permission fees							\$2,500
Shipping, phone, fax, photocopies							\$2,500
On-site staffing							\$500
							\$14,000

Funding

Fusion Medical Education has determined that the funding required to complete this project is \$263,975. Fusion respectfully requests, therefore, an unrestricted educational grant of \$263,975 from Cephalon to support this program. The educational grant covers all costs as they relate to the development, organization, and production of the program.

Development of the program commences upon receipt of payment. The grant is payable to:

Fusion Medical Education LLC
800 Township Line Road, Suite 250
Yardley, PA 19067

Additional Funding

The above budget is an estimate and is subject to change. Fusion will periodically review the budget and notify Cephalon immediately if significant changes in project specifications or scope result in additional funding requirements.

Third-party costs may include purchase of published literature or meeting material, permission fees, application fees, travel costs, telephone, postage, freight, etc. Fusion will attempt to negotiate the best rates for the local area, but third-party costs may exceed the budget. Third-party costs exceeding the budget will be passed on to Cephalon at invoice rates.

Cancellation Policy

In the event of cancellation of the project for any reason: (i) Cephalon shall remain obligated to pay Fusion the grant for services performed or for those that became equitably due prior to the effective date of termination, and to pay for services delivered and any third-party costs incurred prior to such date; (ii) any remaining funds shall be reimbursed by Fusion to Cephalon effective as of the date of termination; (iii) all unpaid invoices and past-due balances outstanding as of the effective date of termination shall become immediately due and payable.

Signatures

Fusion Medical Education LLC Date

Cephalon Date

Information in this grant request is valid for 30 days from the date of submission to Cephalon. Signature on this page will constitute acceptance of the terms of this request.

Fusion Contact

Tracy Lasquade
Fusion Medical Education LLC
301 Edgewater Place, Suite 300
Wakefield, MA 01880
Phone 781-246-6646 x116
tracy.lasquade@fusion-meded.com



Exhibit B

ACTIQ Risk Management Program

Provider is aware that ACTIQ® (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- ACTIQ is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- ACTIQ is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.
- ACTIQ is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.



FENTORA Risk Management Program

Provider is aware that FENTORA™ (fentanyl buccal tablet) [C-II] was approved subject to a Risk Minimization Action Plan (RiskMAP). The RiskMAP includes key safety messages that are essential to the safe use of this product. They are:

- FENTORA is indicated for the management of breakthrough pain in patients with cancer who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- FENTORA is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- No misuse of FENTORA should occur.
- Unintended (accidental) exposure to FENTORA should not occur.
- Patients considered opioid tolerant are those who are taking at least 60 mg oral morphine/day, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that FENTORA can be fatal to a child. Keep all units away from children and discard properly.
- FENTORA is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.